

Message Text

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ORIGIN AGRE-00

INFO OCT-01 IO-13 ISO-00 HEW-06 FEA-01 CEA-01 CIAE-00
COME-00 DODE-00 EB-08 FRB-01 H-02 INR-07 INT-05
L-03 LAB-04 NSAE-00 NSC-05 PA-02 AID-05 SS-15
STR-04 ITC-01 TRSE-00 USIA-15 PRS-01 SP-02 OMB-01
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APPROVED BY STR:JSTARKEY
COMMERCE:RSUPPEBLANEY
STATE:RMEYER
LABOR:DWANAMAKER
STR:BSEASTRUM
TREASURY:WWARTHIN

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FM SECSTATE WASHDC
TO USDEL MTN GENEVA

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E.O. 11652: N/A

TAGS: ETRD;EAGR

SUBJECT:NORWEGIAN REQUEST FOR GRAS CLASSIFICATION FOR
HARDENED MARINE FATS

REF:MTN GEN 2214

1. THE NORWEGIANS ARE CONCERNED THAT HARDENED MARINE FATS
ARE NOT "GENERALLY RECOGNIZED AS SAFE"(GRAS) FOR DIRECT
FOOD USES IN THE U.S. BY THE FOOD AND DRUG ADMINISTRATION.
HARDENED MARINE FATS ARE CLASSIFIED AS GRAS, HOWEVER, FOR
INDIRECT USES, I.E. THE MANUFACTURE OF PAPER AND PAPER-
BOARD CARTONS AND CONTAINERS. TWO SEPARATE ISSUES ARE
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INVOLVED WITH THE NORWEGIAN REQUEST: FIRST, THE ELIGIBIL-
ITY OF HARDENED MARINE FATS FOR GRAS CLASSIFICATION; AND
SECOND, ALLOWABLE USES OF THESE FISH OILS IN THE U.S.
AFTER GIVEN GRAS STATUS.

2. ELIGIBILITY FOR GRAS: WHEN THE FDA FIRST LISTED FOOD
SUBSTANCES TO BE INCLUDED IN THE GRAS FOR HUMAN CONSUMP-

TION CATEGORY IN 1958, THERE WAS NO EXPRESSED INDUSTRY INTEREST FOR INCLUDING FISH OILS IN THIS LIST. THEREFORE FISH OILS WERE NOT INCLUDED AND THUS WERE NOT GIVEN GRAS STATUS. TO ADD A FOOD SUBSTANCE NOW TO THE GRAS LIST REQUIRES THAT THE INTERESTED PARTY PETITION FDA FOR GRAS AFFIRMATION AS STIPULATED IN TITLE 1, PART 121.40 OF THE

CODE OF FEDERAL REGULATIONS (TO BE HAND CARRIED TO DEL), OR PETITION THE FDA PROPOSING REGULATIONS FOR FOOD ADDITIVES AS STIPULATED IN PART 121.51 OF THE SAME CODE. THESE REQUIREMENTS APPLY TO BOTH DOMESTIC AND FOREIGN PETITIONERS. THE FDA REGULATIONS CONCERNING ELIGIBILITY, FOR GRAS CLASSIFICATION ARE VERY DETAILED, BUT IN ESSENCE SAY THAT THE BURDEN OF PROOF OF SAFETY FOR FOOD USE IS ON THE PETITIONER FOR ALL FOOD SUBSTANCES THAT WERE NOT WIDELY CONSUMED IN THE U.S. PRIOR TO JANUARY 1;1978.

3. ALLOWABLE USES: THE FDA ESTABLISHED A STANDARD OF IDENTITY FOR OLEO-MARGARINE WHICH DID NOT INCLUDE FISH OIL BECAUSE NO ONE ASKED FOR FISH OIL TO BE INCLUDED. TODAY, THEREFORE, FISH OILS CANNOT BE LEGALLY INCLUDED IN MARGARINE IN THE U.S., EVEN THOUGH USED EXTENSIVELY ABROAD FOR THIS PURPOSE. IN ORDER TO CHANGE THE FDA STANDARD OF IDENTITY FOR OLEO MARGARINE, THE INTERESTED PARTY MUST PETITION THE FDA UNDER THE PROCEDURES OUTLINED IN PART 10 TITLE 21 OF THE CODE OF FEDERAL REGULATIONS. A SUCCESSFUL PETITION MUST PROVE THAT A CHANGE IN THE STANDARD OF IDENTITY WOULD BE BOTH IN THE INTEREST OF FAIR DEALING AND IN THE INTEREST OF CONSUMERS. IF GIVEN UNCLASSIFIED

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GRAS STATUS, HYDROGENATED FISH OILS MAY LEGALLY BE INCLUDED IN SHORTENING IN THE U.S. HOWEVER, FISH OILS USED FOR SHORTENING MUST HAVE BEEN PROCESSED IN A PLANT THAT HAS MET FDA REQUIREMENTS. THIS IS A CONDITION THAT FEW, IF ANY, U.S. PLANTS SATISFY AT PRESENT.

4. THUS, EVEN IF FISH OIL IS GIVEN GRAS STATUS, THE NORWEGIANS WOULD FIND THAT TWO POTENTIALLY BIG MARKETS, WOULD NOT BE OPEN TO THEM FOR U.S. INTEREST; MARGARINE PRODUCTION BECAUSE THE CURRENT FDA STANDARD OF IDENTITY FOR O OLEO MARGARINE DOES NOT INCLUDE FISH OIL; AND THE U.S. SHORTENING MARKET BECAUSE FISH INTERESTS DO NOT SEEM ABLE TO MEET THE STRICT FDA SANITATION REQUIREMENTS. VANCE

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Message Attributes

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Capture Date: 01-Jan-1994 12:00:00 am
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Control Number: n/a
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Sent Date: 19-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
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Disposition Event:
Disposition History: n/a
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Drafter: 5081:JT4/19/77
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
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Format: TEL
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Handling Restrictions: n/a
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